K070209

510(K) SUMMARY

AUG - 8 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. **Submitter's Name:** **FEGO Precision Industrial Co., Ltd.**
   Address: 947 Lin-Sen Rd., Wu-Fong, Taichung County., 413 Taiwan, R.O.C.
   Phone: +886-4-23391802
   Fax: +886-4-23399374
   Contact: Mr. Bruce Chang / General Manager

2. **Device Name :**
   Trade Name: **FB-100U Series DIGITAL Blood Pressure Monitor**
   (Model No.: **FB-1XYU , XY=00 ~ 99 represent type of case housing**)
   Common Name: **Non-Invasive Blood Pressure Monitor**
   Classification name System , Measurement , Blood-Pressure , Non-Invasive

3. **DEVICE CLASS** **FB-100U Series DIGITAL Blood Pressure Monitor** have been classified as
   Regulatory Class: II
   Panel: 74
   Product Code: DXN
   Regulation Number: 2ICFR 870.1130

4. **Predicate Device:** The predicate device is the Rossmax Automatic Blood Pressure Monitor(K021225) marketed by ROSSMAX INTERNATIONAL LTD.

5. **Device Description:** **FB-100U Series DIGITAL Blood Pressure Monitor** is designed to measure the systolic and diastolic blood pressure, and pulse rate(heart of an individual). All values can be read out in one LCD DISPLAY. Measurement position is on adult arm only.

   FB-100U Series DIGITAL Blood Pressure Monitor meets the requirements specified in ANSI/AAMI SP-10 – Manual, electronic, or automated sphygmomanometers. Full responsibility for the conformance of this product to standard is assumed by **FEGO Precision Industrial Co., Ltd.**

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6. Intended Use: **FB-100U Series DIGITAL Blood Pressure Monitor** is intended to measure the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the upper arm.

The device is indicated for use by people over 15 years old in home use.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ANSI/AAMI SP-10, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

FB-100U Series DIGITAL Blood Pressure Monitor has the same intended use and similar technological characteristics as the Rossmax Automatic Blood Pressure Monitor(K021225) marketed by ROSSMAX INTERNATIONAL LTD.. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, **FB-100U Series DIGITAL Blood Pressure Monitor** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2007

Fego Precision Industrial Co. Ltd.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, AZ 86001

Re: K070209
Trade/Device Name: FB-100U Series Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: July 17, 2007
Received: July 19, 2007

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070209

Device Name: **FB-100U Series Digital Blood Pressure Monitor**
FEGO Precision Industrial Co., Ltd.

Indications For Use:

FB-100U Series Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the upper arm.

The device is indicated for use by people over 15 years old in home use.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070209